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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,312	06/23/2003	Yair Assaf	25523	7520
20529	7590	12/15/2005		
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314				
EXAMINER MENDEZ, MANUEL A				
ART UNIT		PAPER NUMBER		
3763				

DATE MAILED: 12/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/601,312	Applicant(s) ASSAF, YAIR	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21, 39 and 40 is/are pending in the application.
- 4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 39 and 40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Objections

Claim 14 is objected to because of the following informalities: It is not clear whether claim 14 was cancelled or amended. The examiner will treat this claim as amended; however, clarification on this matter is respectfully requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Sarkis, et al., in view of Violante, et al., and in further view of Zhu, et al., Mackoviac, et al., and Weldon, et al.**

Issue I: Coating with a Heavy Metal

In relation independent claims 1 and 14, the applicant argued in the last amendment, that Sarkis, et al., is different from the claimed invention since it discloses an improvement of ultrasound visibility by means of an echogenic material comprising "a plastic impregnated with sonically reflective particles". As discussed in the previous office action, Sarkis, et al., discloses a medical device for insertion into human body having an echogenic portion of enhanced visibility. Importantly, the examiner is using this patent to demonstrate that it is well known to enhance medical infusion devices with echogenic portions in order to increase visibility. Additionally, in response to the

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applicant's concern, it is noted that improving ultrasonic visibility by coating with a heavy metal is conventional in the art as evidenced by the teachings of Violante, et al.

The Violante, et al., patent discloses coatings to enhance the echogenicity of materials especially useful for medical devices wherein the practitioner desires to locate or visualize a device within the body.

Column 11, lines 30-40:

Substrates to which echogenic coatings according to the invention may be applied include metals such as stainless steel, nickel, gold, chrome, nickel titanium alloy, platinum and others; plastics such as silicone, polyurethane, polyethylene, polyamide, polyvinylchloride, latex and others; drug particles; and capsules. Preferred devices include needles, guidewires, catheters, surgical instruments, equipment for endoscopy, wires, stents, angioplasty balloons, wound drains, arteriovenous shunts, gastroenteric tubes, urethral inserts, laparoscopic equipment, pellets, or implants.

More importantly, Violante et al., discloses the use of coatings that include, for example, metals such as gold, which would inherently have a density greater than 12 g/cc since claim 16 specifically claims gold as one of the metals that has a density greater than 12 g/cc and 15 g/cc.

Based on the above persuasive evidence, modifying the infusion apparatus disclosed by Sarkis, et al., with a coating with a heavy metal having a density greater than 12 or 15 g/cc as taught by Violante, et al., would have been considered obvious in view of the proven conventionality of this enhancement(s). Furthermore, these enhancement(s) would have increased the accuracy of the infusion system resulting in a safer medical environment.

Issue II: The Infusion of a Blood-Clotting Agent using an Infusion Device

The Sarkis, et al., patent demonstrates the conventionality of using an infusion medical device having echogenic coatings to infuse substances into the body. Despite being capable, Sarkis, et al., does not expressly disclose the infusion of blood-clotting agents into the body. However, the use of tubular infusion devices to infuse blood-clotting agents is conventional in the art as evidenced by Zhu, et al., and Weldon, et al.

Zhu, et al., discloses the use of blood clotting agents. Additionally, in column 2, lines 5-7, the patent recognizes the importance blood clotting to prevent aneurysms, which increase the risk of infection and reopening. Additionally, Weldon, et al., further demonstrates that it is well known to infuse blood clotting agents into the body using tubular medical devices.

Based on the evidence presented above, modifying the apparatus disclosed by Sarkis, et al., with the capability of infusing a blood clotting agent would have been obvious in view of the proven conventionality of this enhancement. Additionally, this modification would have expanded the capabilities of the infusion apparatus disclosed by Sarkis, et al., resulting in a more efficient working environment.

In relation to claims 2-13 and 15-21 the subject matter disclosed is considered inherent characteristics of a heavy metal coating such as gold. Additionally, concerning the thickness of the coating, such enhancement is directly related to the desired echogenicity. Therefore, claim limitations suggesting specific thickness should not be given patentable weight in view of the fact that these limitations are limited and conceived by the intended use of the infusion apparatus in the body.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

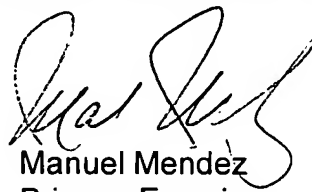
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez
Primary Examiner
Art Unit 3763

MM